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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/836,455	05/09/97	CHATTERJEE M	304142000322

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EXAMINER	
BURKE, J	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/836,455	Applicant(s) Chatterjee et al
	Examiner Julie E. Burke, (Reeves), Ph.D.	Group Art Unit 1642

☒ Responsive to communication(s) filed on *8 Feb 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-58* is/are pending in the application.

Of the above, claim(s) *1-5, 20-37, 39, 40, 42, 43, and 46-56* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *6-19, 38, 41, 44, 45, 57, and 58* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Claims 1-5, 20-37, 39-40, 42-43, 46-56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected inventions. Election was made **without** traverse in Paper No. 14.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Claims 6-19, 38, 41, 44-45, 57-58 are under examination.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Request for the corrected filing receipt filed 9 April 1998 is noted, but will not processed due to the fact that the title needs to be changed in view of the election of polynucleotides and withdrawal of the claims directed at methods.

5. The disclosure is objected to because of the following informalities:

6. On page 8, line 28, the ATCC address is incorrect and needs to be rewritten as

--10801 University Boulevard, Manassas, VA 20110-2209--

The text of the specification contains blanks on page 1, lines 6-8, page 8, line 32 and page 46, line 29.

The continuing data on the first line of the specification needs to be amended to recite that the instant application is a 371 national stage filing of PCT/US96/20757, filed 12/19/96 and to recite the priority for 08/766,350 filed 13 Dec 1996.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

7. Claims 6-19, 38, 41, 44-45, 57-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 6-13, 16-19, 38, 41, 44-45, 57-58 are indefinite for reciting "polypeptide having immunological activity of monoclonal anti-idiotype antibody 11D10" because it is not clear what sort of immunologic activity (antigenicity? Immunogenicity? Effector functions? All 11D10 immunological activities?) is being claimed. If the peptide can be used to raise an antibody specific for 11D10, would that be considered an immunologic activity? The metes and bounds of the claims cannot be determined.

b. Claims 6-13, 16-19, 38, 41, 44-45, 57-58 are indefinite in the recitation of "11D10" because other laboratories/inventors may use the same laboratory designation to refer to

different antibodies. Amendment of the claim to insert the corresponding ATCC accession number would overcome this rejection.

c. Claims 9-12 are indefinite for reciting "sequence is depicted within" because it is not clear whether the term "depicted in" means consisting of or comprising the sequence or refers to portions within the sequence.

d. Claim 13 is indefinite for reciting "complementarity defining region" because it is not clear what is meant by the term "defining". Is the claim meant to recite "complementarity determining region"?

e. Claims 14-15 and 57-58 are indefinite for reciting "said region capable of forming a stable duplex with... under conditions where the region does not form a stable hybrid with SEQ ID NO: 5 through 14", for example for the following six reasons.

It is not clear what is meant by the term "capable"-- under what circumstances would the region be capable of forming a stable duplex? Does the region form or not form a stable duplex/hybrid?

Second, it is not clear what conditions are being claimed-- are particular hybridization conditions meant? If DNA comprising SEQ ID NO: 1 is in a separate jar than a DNA comprising SEQ ID NO: 5, is that a condition where the regions do not form stable duplex/hybrid?

Third, which 15 contiguous nucleotides of which sequences are forming the stable duplex/hybrid? Or do the claims intend to mean that a 15-mer forms a stable duplex/hybrid with the full length SEQ ID NO: 1, for example or with 15-mer portions of SEQ ID NO: 1?

Fourth, what is the difference between the stable duplex and the stable hybrid? What are the metes and bounds of these terms?

Fifth, is the region expected to form a stable hybrid with all of SEQ ID NO: 5 through 14, simultaneously and inclusively, or do the claims mean to recite "where the region does not form a stable hybrid with a polynucleotide molecule consisting of SEQ ID NO: 5, 6, 7, 8,9 ,10, 11, 12, 13 or 14"? A similar argument is made for claim 15.

Sixth, how can a molecule form a hybrid/duplex with a sequence? The term "sequence" refers to information describing the nucleic acid or amino acid sequence. Information is not a chemical structure, therefore, it is not clear how "sequences" can form hybrids with nucleic acid molecules.

f. Claim 38 is indefinite for reciting "a pharmaceutical composition" because it is not clear what is meant by this intended use phrase "pharmaceutical". If the composition is used for a diagnostic test, is it a pharmaceutical composition? Deleting the term "pharmaceutical" would obviate this rejection.

g. Claims 38 and 41 are indefinite for reciting "effective amount". The phrase "an effective amount" is indefinite when the claim fails to state the function which is to be achieve. In re Frederiksen, 213 F 2d 547, 102 USPQ 35 (CCPA 1954).

8. Claims 6-19, 38, 41, 44-45, 57-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides which encode the entire 11D10

variable domains, does not reasonably provide enablement for vaccines, and polynucleotide encoding portions of 11D10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

a. Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

b. Claims 6-19, 38, 41, 44-45, 57-58 are directed to polynucleotides comprising a sequence encoding a polypeptide having immunologic activity of 11D10, wherein the polypeptide comprises at least five contiguous amino acids of a variable region of 11D10. Please see various rejections set forth under 35 U.S.C. 112, second paragraph.

c. Claims 14-15 and 57-58 are drawn to polynucleotides which are "capable" of forming a "stable duplex" with a polynucleotide consisting of SEQ ID NO: 1 or 3, "under conditions where the region does not form a stable hybrid with SEQ ID NO: 5 through 14 or 15 through 32". The specification does not teach what conditions are used to determine the metes and bounds of the claims, therefore, one skilled in the art would not be able to make and use the claimed polynucleotides without undue experimentation.

d. Claims 38, 41, 44 and 45 are directed towards a vaccine comprising an effective amount of the polynucleotide of claim 6. A vaccine or a method of using a vaccine implies that the treated animal is protected against subsequent infection. In re Wright, 27 USPQ2d 1510 (Fed Cir 1993). The phrase "effective amount" is indefinite when the claims fail to state the function which is to be achieved. See In re Frederiksen & Nielsen, 213 F 2d 547, 102 USPQ 35 (CCPA 1954). The claims broadly encompass any polynucleotide which comprises a sequence encoding 5 contiguous amino acids of variable region of 11D10. The claims read upon polynucleotides which encode five amino acids from the framework regions and are not limited to polynucleotides encoding the 11D10 unique complementarity determining regions. Even if the claims were limited to the CDRs, it is not clear that the CDRS provide the immunological activity of 11D10. Immunological activity encompasses effector functions, antigenicity and Immunogenicity in addition to antigen binding activity.

e. It is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having

antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc Natl Acad Sci USA 1982 Vol 79 page 1979). Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that fusion proteins as defined by the claims which may contain less than the full complement of CDRs from the heavy and light chain variable regions of an 11D10 antibody in unspecified order and fused to any human or nonhuman framework sequence, have the required binding function. The specification provides no direction or guidance regarding how to produce fusion proteins and antibodies as broadly defined by the claims. Undue experimentation would be required to produce the invention commensurate with the scope of the claims from the written disclosure alone. Further, the specification does not teach that a functional humanize antibody can be obtained by replacing the CDR regions of an acceptor antibody with the CDRs of a donor antibody. Panka et al (Proc Natl Acad Sci USA Vol 85 3080-3084 5/88) demonstrate that a single amino acid substitution of serine for alanine results in decreased affinity. In at least one case it is well known that an amino acid residue in the framework region is involved in antigen binding (Amit et al Science Vol 233 747-753 1986).

f. Although it can be argued that polypeptide encoding a polypeptide having (some or all?) immunological activity of anti-idiotypic antibody 11D10 are necessary for enablement of a

vaccine, it is unpredictable whether such activity is sufficient to enable a vaccine, particularly in view of the minimal guidance in the specification regarding a predictive link or nexus between such responses and the treatment or prevention of any disease.

g. The specification discloses on page 65-66, that immunization with the entire 11D10 antibody was sufficient to raise an anti-idiotypic antibody response, however, the specification fails to teach that immunization with portions of 11D10 as small as five amino acids, would be sufficient to have the immunologic activity of 11D10. The specification also teaches that the entire 11D10 antibody induces specific immune response against a distinct and specific epitope of human milk fat globule, a breast cancer associated antigen (page 8, lines 23-25), however the specification fails to show any preventive or therapeutic responses sufficient to enable the claimed vaccine.

h. The specification fails to teach any five mer peptide of 11D10 would be effective in any method of therapy or prophylaxis. Moreover, the specification has failed to offer guidance and/or working examples as to which of the myriad of five-mer peptides would be sufficient to confer protective immunity, i.e., illicit neutralizing antibodies capable of preventing infection, in response to breast cancer.

i. Neither is the use of 11D10, or similar anti-idiotype antibodies, as vaccines according to the instant invention considered routine in the art. Browning et al. (Cell Vol 72 847-856 3/93) teaches that "The initiation of the immune response involves a complex array of intercellular signals, usually soluble cytokines coupled with a number of cell-cell-contact-

dependent signals." (p. 847, paragraph 1). The specification does not provide guidance sufficient to enable the skilled artisan to link, in a predictable way, the use of portions of the antibody 11D10 as a vaccine and the stimulation of a protective immune response therewith. In view of this limited guidance, the skilled artisan is presented with a multitude of diseases against which the "vaccine" must be evaluated, with few facts upon which a prediction of efficacy may be made. Therefore, in view of the insufficient guidance in the specification, and unpredictability in the art, undue experimentation would be required to enable the claims.

j. Similarly, the specification fails to enable any form of attenuation or inactivated of the antigens or sub-fragment thereof using portions of the 11D10 variable region, including portions as small as 5 amino acids and portions from the framework regions. Development of a vaccine and method of therapy or prophylaxis is considered to be highly unpredictable in the viral immunology art and the specification lacks any sort of working example or adequate written description to enable the claimed vaccines or method or treatment or prophylaxis. In view of the inadequate guidance and/or teachings in the specification, taken in view f the insufficient working examples, further in view of the breadth of the claims and the unpredictability of the art as evidenced by Browning et al, Amit et al, Rudikoff et al, Panka et al, it would require undue experimentation for the skilled artisan to practice this invention. Ex parte Forman, 230 USPQ 546 (B.P.A.I. 1986).

k. Further, the disclosure does not provide working examples wherein all of the steps required to practice the method are employed. Lack of working examples is given added weight

in cases involving an unpredictable and undeveloped art such as the treatment of cancer with portions of an anti-idiotypic antibody. In the instant case, the claims are so broadly drawn, the guidance is so limited, and the art is so unpredictable that skilled artisan is presented with a multitude of un-linked alternatives with no guidance as to which will enable use of the invention as claimed. Among these are (i) which fragments to use (light chain? Heavy chain? CDR sequences? Framework sequences?), (ii) which of the many five-mer sequences to select, and (iii) which of the many immunologic activities of 11D10 to select for to provide a polynucleotide encoding a polypeptide having the immunologic activity of 11D10.

1. Amending the claims to

(1) recite polynucleotides encoding the entire 11D10 variable regions (heavy and light chains, including all six CDRs) in independent claims,

(2) recite the particular "immunologic activity" in independent claims,

(3) replacing the "stable duplex" language with particular hybridization conditions in claims 14-15,

(4) remove the term "pharmaceutical from claim 38,

(5) replace the term "vaccine in claims 41, 44 and 45 with "immunogenic composition" or similar language which is supported by the specification and

(6) define or remove the phrase "effective amount from claims 38 and 41 would obviate this rejection.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (f) he did not himself invent the subject matter sought to be patented.

10. Claims 6, 8, 10, 12, 13, 15, 16-17, 19, 38, 41, 44, 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Mo et al (Eur J Immunol 1993 Vol 23, 2503-2510), as evidenced by the attached computer sequence alignment.

a. The claims recite a isolated polynucleotide comprising a sequence encoding a polypeptide having immunologic activity of mAb 11D10, wherein the polypeptide comprising at least 5 contiguous amino acids of a variable region of 11D10, wherein the variable region is from a heavy chain, wherein the 5 contiguous amino acids are depicted in SEQ ID NO: 4, or is encoded by SEQ ID NO: 3, or are in a CDR. Further embodiments include sequences which are capable for forming a stable duplex with SEQ ID NO: 3 under conditions where the region does not form a stable hybrid with SEQ ID NO: 15-32, wherein the polynucleotide is a cloning vector, expression vector or is in a host cell. Other embodiments include pharmaceutical compositions, vaccines and kits.

b. In view of the various rejections set forth under 35 U.S.C. 112, second paragraph, above, the claims are being interpreted broadly to mean any polynucleotide which encodes any 5-mer region of 11D10. The phrase "immunologic activity" is being interpreted to mean any immunogenic activity, including antigenicity. "Complementarity defining regions" are being interpreted as "complementarity determining regions". Because claims 38 and 41 fail to include any limitation for the phrase "effective amount", these claims are being interpreted broadly as meaning any effective amount, for example, effective to raise an immune response.

c. Mo et al teach polynucleotides which encode a polypeptide comprising at least five amino acids of the 11D10 heavy chain variable region, including five amino acids from the 11D10 heavy chain CDR 1 (SYNMH). See Figure 3. One skilled in the art would reasonably conclude that immunization with Mo et al's polypeptide would result in antibodies which also bind to the 11D10 antibody. Thus the limitations of the claims have been met.

11. Claims 6, 8, 10, 12, 13, 15, 16-17, 19, 38, 41, 44, 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Gourlie et al (5,808,033, filed 2/93 and issued 9/98).

a. The claims have been described above.

b. Gourlie et al teaches the sequences VRSGA which exactly matches the sequence VRSGA (31-35) consisting of CDR1 of SEQ ID NO: 4. See residues 12-16 of Gourlie et a;'s SEQ ID NO: 3 and MPSRCH sequence printout. Sequence VRSGA is designated as CDR1 of an antibody heavy chain. Thus the limitations of the claims have been met.

12. Claims 6, 8, 10, 12, 13, 15, 16-17, 19, 38, 41, 44, 58 are rejected under 35 U.S.C. 102(b) as being anticipated by either Liu et al (J Immunology Vol 139 3521-3526 No 10 15 Nov 1987) or De Waele et al (Eur J Biochem Vol 176 287-295 1988) as evidenced by the attached computer sequence alignment.

a. The claims have been described above.

b. Liu et al teach polynucleotides which encode a polypeptide comprising at least five amino acids of the 11D10 heavy chain variable region, including five amino acids from the 11D10 heavy chain CDR 2 (Tyr Asn Gln Lys Phe Lys Gly, see Figure 1A). One skilled in the art would reasonably conclude that immunization with Liu et al's polypeptide would result in antibodies which also bind to the 11D10 antibody. Thus the limitations of the claims have been met..

c. De Waele et al teach polynucleotides which encode a polypeptide comprising at least five amino acids of the 11D10 heavy chain variable region. See Figure 3. One skilled in the art would reasonably conclude that immunization with De Waele et al's polypeptide would result in antibodies which also bind to the 11D10 antibody. Thus the limitations of the claims have been met.

13. Claims 6, 7, 9, 11, 14, 16-17, 19, 38, 41, 44, 57 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Shlomchik et al (J Exp Med Vol 171 1/90 265-297); Kavaler et al (J Immunology Vol 145 2312-2321 No 7 10/90), Seidman et al (Nature Vol 280 370-375 1979), or

Darsley et al (EMBO J Vol 492) 393-398 1985) as evidenced by the attached computer sequence alignment.

a. The claims recite a isolated polynucleotide comprising a sequence encoding a polypeptide having immunologic activity of mAb 11D10, wherein the polypeptide comprising at least 5 contiguous amino acids of a variable region of 11D10, wherein the variable region is from a light chain, wherein the 5 contiguous amino acids are depicted in SEQ ID NO: 2, or is encoded by SEQ ID NO: 1. Further embodiments include sequences which are capable for forming a stable duplex with SEQ ID NO: 1 under conditions where the region does not form a stable hybrid with SEQ ID NO: 5 through 14, wherein the polynucleotide is a cloning vector, expression vector or is in a host cell. Other embodiments include pharmaceutical compositions, vaccines and kits.

b. Shlomchik et al teach polynucleotides which encode a polypeptide comprising at least five amino acids of the 11D10 light chain variable region. See page 270 One skilled in the art would reasonably conclude that immunization with Shlomchik et al's polypeptide would result in antibodies which also bind to the 11D10 antibody. Thus the limitations of the claims have been met.

c. Kavaler et al teach polynucleotides which encode a polypeptide comprising at least five amino acids of the 11D10 light chain variable region. See Figure 5. One skilled in the art would reasonably conclude that immunization with Kavaler et al's polypeptide would result in

antibodies which also bind to the 11D10 antibody. Thus the limitations of the claims have been met.

d. Seidman et al teach polynucleotides which encode a polypeptide comprising at least five amino acids of the 11D10 light chain variable region. See Figure 4. One skilled in the art would reasonably conclude that immunization with Seidman et al's polypeptide would result in antibodies which also bind to the 11D10 antibody. Thus the limitations of the claims have been met.

e. Darsley et al teach polynucleotides which encode a polypeptide comprising at least five amino acids of the 11D10 light chain variable region. See Figure 2. One skilled in the art would reasonably conclude that immunization with Darsley et al's polypeptide would result in antibodies which also bind to the 11D10 antibody. Thus the limitations of the claims have been met.

14. Claims 6, 7, 9, 11, 13, 14, 16-17, 19, 38, 41, 44, 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Bendig et al (5,840,299, filed 11/95 and issued 11/98).

a. The claims 6, 7, 9, 11, 14, 16-17, 19, 38, 41, 44, 57 have been described above.

b. Claim 13 recites a isolated polynucleotide comprising a sequence encoding a polypeptide having immunologic activity of mAb 11D10, wherein the polypeptide comprising at least 5 contiguous amino acids of a variable region of 11D10, wherein the 5 contiguous amino acids are in a CDR.

c. Bendig et al teach an antibody comprising the sequence MTQSPSSLSAS which exactly matches the amino acid residues 24-34 of SEQ ID NO: 2, CDR 1 of 11D10 light chain. See residues 4-14 of Bendig et al Fig 1A or residues 24-34 of SEQ ID NO: 1 and MPSRCH sequence printout. Thus the limitations of the claims have been met.

15. Claims 6-17, 19, 38, 41, 44, 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by any of

i. Chatterjee et al Antigen and Antibody Molecular Engineering 1994 (see page 140, Fig 1, for example)

ii. Chatterjee et al Cancer Immunol Immunother 1994 Vol 34 75-82 (See page 77, last full paragraph, for example)

iii. Chakraborty et al Proc Am Assoc Cancer Res 1994 Abstract 2963 (See Abstract); or

iv. Chakraborty et al 1995 J Immunotherapy Vol 18(2) 95-103 (see page 96, col 1 "Antibodies")

a. Claims 6-17, 19, 38, 41, 44, 57-58 have been described above. It is noted that Section 102(b) contains the clause the invention was "described in a printed publication in this or a foreign country". Although the DNA sequence encoding the 11D10 mAb was not disclosed in these references, the DNA is considered an inherent property of the hybridoma expressing the

11D10 mAb. This invention was clearly described in a publication more than one year prior to the date of application for patent in the United States.

16. Claims 6-17, 19, 38, 41, 44, 57-58 are rejected under 35 U.S.C. 102(f) as by any of Chatterjee et al (Antigen and Antibody Molecular Engineering 1994), Chatterjee et al (Cancer Immunol Immunother 1994 Vol 34 75-82), Chakraborty et al (Proc Am Assoc Cancer Res 1994 Abstract 2963) or Chakraborty et al (1995 J Immunotherapy Vol 18(2) 95-103 (see page 96, col 1 "Antibodies") because the inventors did not invent the work sought to be patented.

a. Claims have been described above. The instant application lists M. Chatterjee; K. Foon and S. Chatterjee as the sole inventors of the polynucleotides encoding portions of the 11D10 variable region.

b. In contrast, Chatterjee et al (Antigen and Antibody Molecular Engineering 1994) lists not only M. Chatterjee and K.Foon; but also lists E. Mrozek; S. Mukerjee; R. Ceriani and H. Kohler as authors on a paper discussing the 11D10 antibody. Similarly, Chatterjee et al (Cancer Immunol Immunother 1994 Vol 34 75-82) lists H. Kohler as an author but not an inventor. Additionally, Chakraborty et al (Proc Am Assoc Cancer Res 1994 Abstract 2963) list as authors, but not inventors, the following: M. Chakraborty, A. Sherratt and K. Ceriani.

c. From the authorship lists recited above, one skilled in the art would reasonably conclude that in addition to M. Chatterjee; K. Foon and S. Chatterjee; the authors M.

Chakraborty, H. Kohler, A. Sherratt, Mrozek; S. Mukerjee; R. Ceriani also contributed to the invention. They are not listed as inventors. Thus the rejection is made.

Double Patenting

17. Claim 19 of this application conflict with claim 3 of Application No. 08/836,455. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claim 19 is provisionally rejected under the judicially created doctrine of double patenting over claim 3 of copending Application No. 08/766,350. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the host cell comprising polynucelotides sequences encoding 11D10 amino acid sequences reads upon the hybridoma which expressed the 11D10 antibody.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie E. Burke, née Reeves, Ph.D, whose telephone number is (703) 308-7553. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

22. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Julie E. Burke, née Reeves, Ph.D.

Patent Examiner

(703) 308-7553

JULIE REEVES
PATENT EXAMINER